

**REMARKS**

The above amendments have been provided based on the format described at 1265 Off. Gaz. Pat. Office 87 (December 17, 2002) and as authorized by Deputy Commissioner for Patents, Stephen Kunin on January 31, 2003.

Claims 25 and 45-70 are currently pending. Claim 27 is cancelled. Claim 25 is amended herein. Support for the amendment to claim 25 is found in throughout the specification, *e.g.*, at page 7, lines 6-7, page 17, lines 9-20 and Example 5, and therefore it is believed that no new matter is added. To date, no claim is allowed.

**Formal Matters**

Applicants gratefully acknowledge the granting of the Interview with the Examiner on May 9, 2003. Applicants address herein issues related to this case as discussed with the Examiner as well as other pertinent issues.

Applicants note that the Petition to Make Special was filed in this application on January 15, 2002. To date, Applicants have received no notification that this Petition has been considered, and therefore, a Renewed Petition to Make Special is filed herein. Applicants direct the Examiner's attention to *Manual of Patent Examination Procedure* § 708.03 (XII) (8th ed. 2001) which states:

[e]ach petition to make special, regardless of the ground upon which the petition is based and the nature of the decision, **is made of record in the application file, together with the decision thereon.**

Applicants note that claim 27 has not been canceled by Applicants or withdrawn by Examiner in prior Actions. Claim 27 is canceled herein.

According to the Advisory Action dated March 13, 2003, the submitted Exhibits have not been considered because they are "not directed SOLELY to issues which were newly raised by the Examiner in the final rejection." Applicants note that Exhibits B-K were not newly submitted, but rather as replacements for the Exhibits submitted with the Amendment dated July 29, 2002 because the Examiner alleged that they were not in the file. Applicants note that the loss of the Exhibits did

not change the Examiner's obligation to consider all evidence presented by Applicants, particularly the evidence submitted with the Response to the First Action dated April 29, 2002. Manual of Patent Examination Procedure § 2164.05. "[T]he Examiner must ... weigh all evidence before him" and "[a] declaration or affidavit is, itself, evidence that must be considered", and therefore, consideration of the submitted evidence by the Examiner is required. *Manual of Patent Examination Procedures* § 2164.05 (emphasis in original). Thus, Applicants respectfully request a full, careful, and timely consideration of all of the evidence now before the Examiner. **If the Examiner continues to lack copies of the Exhibits, he is requested to contact the undersigned and a third copy will be provided by Hand Delivery.**

As discussed with the Examiner in the Interview on May 9, 2003, Applicants now provide a copy of the original Information Disclosure Statement and a copy of only those references not included in the Information Disclosure Statement of the related case, Application Serial No. 09/421,545. The Examiner is respectfully requested to consider the references listed in the Information Disclosure Statement.

Finally, Applicants ask that the Examiner identify allowable subject matter in the first Action on the merits. *See Manual of Patent Examination Procedure* § 2164.04 ("the examiner should always look for enabled, allowable subject matter and communicate to applicant what that subject matter is at the earliest point possible in the prosecution of the application") (emphasis included).

### **Rejections Under 35 U.S.C. § 112**

Claims 25 and 45-70 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to provide enablement for a compound that inhibits proteasomal activity or that inhibits the chymotrypsin-like activity of the proteasome for reasons of record. Claims 25 and 45-70 also stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Applicants respectfully traverse this rejection for reasons of record and the additional reasons discussed below.

Again, Applicant respectfully submit that the patentability of the instant invention lies not in the invention of the compounds that inhibit proteasomal activity, but rather in knowing what to do with these proteasomal inhibitors. In other words, the patentability lies in the novelty of the method

disclosed and not in the compounds themselves.

Applicants note that functional claim language is expressly recognized as proper claim language in the case law. Specifically, if a compound must retain a certain biological activity to be within the scope of the claimed invention, and one of skill in the art is clearly enabled to perform assays to determine such biological activity using routine experimentation disclosed in the specification, the disclosure is fully enabling. *Ex Parte Mark*, 12 U.S.P.Q.2d 1904 (Bd. Pat. App. & Int. 1989) (holding that method claims to produce biologically active muteins by modifying biologically-nonessential cysteines was fully enabled because any mutein within the scope of the claims must have retained its biological activity and the experimentation required to determine biological activity for any given mutein was routine for one of ordinary skill in the art). *See Exhibit A*. The compound of the claimed methods is one that is a proteasomal inhibitor. Proteasomal inhibition is a certain biological activity that a compound must possess to be within the scope of the claimed methods. Therefore, the compound of the claimed methods falls squarely within the holding of *Ex Parte Mark*. If the Examiner believes that *Ex Parte Mark* does not apply to the instant claims, Applicants respectfully request the Examiner provide specific findings of fact, supported by evidence, and then conclusions based on those findings of fact supporting this position. *Manual of Patent Examination Procedure* § 2164.04 (“[s]pecific technical reasons are always required” for an enablement rejection).

Applicants further note that functional claim language is expressly recognized as proper claim language in the *Manual of Patent Examination Procedure*. It states

[a] functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). **There is nothing inherently wrong with defining some part of an invention in functional terms.** Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 U.S.P.Q. 226 (CCPA 1971).

*Manual of Patent Examination Procedure* § 2173.05(g) (emphasis added). Again, Applicants request specific findings of fact and conclusions based on those findings to support the Examiner’s position that the instant claims cannot employ functional language.

Finally, Applicants note that Examiner Gitomer has, in fact, allowed functional claims in a recent patent issued in January 2003. In U.S. Patent No. 6,511,800 B1, each independent claim contains functional language where the patented method of treatment employs compounds defined

only by a shared biological activity. For example, Claim 1 reads:

A method of treating a nitric oxide or cytokine mediated disorder in a cell, comprising administering a biologically effective amount of at least one induction suppressor of an inducible nitric oxide synthase or a cytokine, wherein said induction suppressor is an inhibitor of mevalonate synthesis, an inhibitor of the farnesylation of Ras, an antioxidant, an enhancer of intracellular cAMP, an enhancer of protein kinase A (PKA), an inhibitor of NF- $\kappa$ B activation, an inhibitor of Ras/Raf/MAP kinase pathway, an inhibitor of mevalonate pyrophosphate decarboxylase or an inhibitor of farnesyl pyrophosphate.

No structures are provided in this claim or the other independent claims. No degree or specificity of inhibition are provided in this claim or the other independent claims. Rather the compounds of the above claim are limited by the shared biological activity of inducing suppression of an inducible nitric oxide synthase or a cytokine. Moreover, the amount of the compound to administered is defined simply as a "biologically effective amount." As in the instant application, an effective amount is defined in terms of biological outcomes easily ascertained by the skilled artisan using the guidance in the specification. Therefore, it appears that the Examiner has allowed claims to methods using an effective amount of compounds defined by a shared biological activity.

In light of the above arguments, Applicants respectfully submit that the rejection of claims 25 and 45-70 under 35 U.S.C. § 112, first and second paragraph be withdrawn.

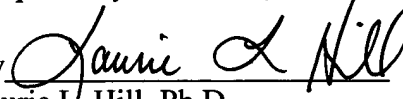
**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

If the Examiner feels that a telephonic conference would be helpful, please call the undersigned at 858-720-7955 at your convenience. In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 43272-2002612.

Dated: May 22, 2003

Respectfully submitted,

By   
Laurie L. Hill, Ph.D.

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UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

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UNITED STATES PATENT AND TRADEMARK OFFICE  
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

MORRISON & FOERSTER LLP  
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PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 02/08/2001

REEL/FRAME: 011512/0908  
NUMBER OF PAGES: 3

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

MUNDY, GREGORY R.

DOC DATE: 01/22/2001

ASSIGNOR:

GARRETT, ROSS I.

DOC DATE: 01/22/2001

ASSIGNOR:

ROSSINI, G.

DOC DATE: 01/22/2001

ASSIGNEE:

OSTEOSCREEN, INC.  
2040 BABCOCK ROAD, SUITE 201  
SAN ANTONIO, TEXAS 78229

SERIAL NUMBER: 09695807

PATENT NUMBER:

FILING DATE: 10/23/2000

ISSUE DATE:

* No Docketing Required *	
Reviewed by Docketing	
Initials	AKB/AMB

Exhibit A

011512/0908 PAGE 2

SHARON LATIMER, EXAMINER  
ASSIGNMENT DIVISION  
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02-20-2001

S. DEPARTMENT OF COMMERCE

RE



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Patent and Trademark Office  
Docket No. 432722002623

101615638

FEB 3

2-8-01

To the Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

## 1. Name of conveying party(ies):

Gregory R. Mundy, Ross I. Garrett, G. Rossini

- ☒ Individual(s)      ☐ Association  
☐ General Partnership      ☐ Limited Partnership  
☐ Corporation-State      ☐ Other

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

## 2. Name and address of receiving party(ies):

Name: OsteoScreen, Inc.

Internal Address:

Street Address: 2040 Babcock Road, Suite 201

City: San Antonio, State: TX ZIP: 78229

Additional name(s) & address(es) attached? ☐ Yes ☒ No

## 3. Nature of conveyance:

- ☒ Assignment      ☐ Merger  
☐ Security Agreement      ☐ Change of Name  
☐ Other:

Execution Date: January 22, 2001 - Gregory R. Mundy

January 22, 2001 - Ross I. Garrett

January 22, 2001 - G. Rossini

## 4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No.(s)

09/695,807

B. Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

## 5. Name and address of party to whom correspondence concerning document should be mailed:

Peng Chen  
Morrison & Foerster LLP  
3811 Valley Centre Drive  
Suite 500  
San Diego, California 92130-2332

## 6. Total number of applications and patents involved: One

## 7. Total fee (37 C.F.R. § 3.41): \$40.00

- ☒ Enclosed  
☐ Authorized to be charged to deposit account, referencing  
Attorney Docket 432722002623

## 8. Deposit account number: 03-1952

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. § 1.21 that may be required by this paper, or to credit any overpayment to Deposit Account No. 03-1952.

## DO NOT USE THIS SPACE

## 9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Name: Peng Chen  
Registration No: 43,543

Signature

Date

Total number of pages comprising cover sheet, attachments and document: Three

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sd-27814



Applicant/Patentee: OsteoScreen, Inc.

Docket No.: 432722002623

Serial No./Patent No.: 09/695,807

Filed on/Issued : October 23, 2000

For: INHIBITORS OF PROTEASOMAL ACTIVITY FOR STIMULATING BONE AND HAIR GROWTH

**VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS  
37 C.F.R. §§ 1.9(f) AND 1.27(c) — SMALL BUSINESS CONCERN**

I hereby declare that I am

- ☐ the owner of the small business concern identified below:  
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: OsteoScreen, Inc.

ADDRESS OF CONCERN: 2040 Babcock Road, Suite 201, San Antonio, TX 78229

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. § 121.12, and reproduced in 37 C.F.R. § 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled INHIBITORS OF PROTEASOMAL ACTIVITY FOR STIMULATING BONE AND HAIR GROWTH by inventor(s) Gregory R. Mundy, I. Ross Garrett and G. Rossini, described in

- ☐ the specification filed herewith with title as listed above.  
☒ the application identified above.  
☐ the patent identified above.

If the rights held by the above identified business concern are not exclusive, each individual, concern or organization having rights in the invention must file separate verified statements averring to their status as small entities, and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 C.F.R. § 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 C.F.R. § 1.9(d), or a nonprofit organization under 37 C.F.R. § 1.9(e).

Each person, concern or organization having any rights in the invention is listed below:

- ☐ no such person, concern, or organization exists.  
☐ each such person, concern or organization is listed below.

NAME	ADDRESS	TYPE
		<input type="checkbox"/> Individual <input type="checkbox"/> Small Business Concern <input type="checkbox"/> Nonprofit Organization

Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. § 1.27)

I acknowledge the duty to file, in this application or patent, notification or any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. § 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING:

Gregory R. Mundy

TITLE OF PERSON IF OTHER THAN OWNER: President

ADDRESS OF PERSON SIGNING:

OsteoScreen, Inc. 2040 Babcock Road, Suite 201  
San Antonio, TX 78229

SIGNATURE: \_\_\_\_\_

DATE: \_\_\_\_\_

## ASSIGNMENT JOINT

THIS ASSIGNMENT, by Gregory R. Mundy, Ross I. Garrett and G. Rossini (hereinafter referred to as the assignors), residing at San Antonio, Texas 78230; San Antonio, Texas 78023, and San Antonio, Texas 78238, respectively, witnesseth:

WHEREAS, said assignors have invented certain new and useful improvements in INHIBITORS OF PROTEASOMAL ACTIVITY FOR STIMULATING BONE AND HAIR GROWTH, set forth in an application for Letters Patent of the United States, having an oath or declaration executed on even date herewith; bearing Serial No. 09/695,807 and filed on October 23, 2000; and

WHEREAS, OsteoScreen, Inc., a corporation duly organized under and pursuant to the laws of Texas and having its principal place of business at 2040 Babcock Road, Suite 201, San Antonio, Texas 78229 (hereinafter referred to as the assignee) is desirous of acquiring the entire right, title and interest in and to said inventions and said application for Letters Patent of the United States, and in and to any Letters Patent or Patents, United States or foreign, to be obtained therefor and thereon:

NOW, THEREFORE, in consideration of One Dollar (\$1.00) and other good and sufficient consideration, the receipt of which is hereby acknowledged, said assignors have sold, assigned, transferred and set over, and by these presents do sell, assign, transfer and set over, unto said assignee OsteoScreen, Inc., its successors, legal representatives and assigns, the entire right, title and interest in and to the above-mentioned inventions, application for Letters Patent, and any and all Letters Patent or Patents in the United States of America and all foreign countries which may be granted therefor and thereon, and in and to any and all divisions, continuations and continuations-in-part of said application, or reissues or extensions of said Letters Patent or Patents, and all rights under the International Convention for the Protection of Industrial Property, the same to be held and enjoyed by said assignee, for its own use and the use of its successors, legal representatives and assigns, to the full end of the term or terms for which Letters Patent or Patents may be granted, as fully and entirely as the same would have been held and enjoyed by the assignors, had this sale and assignment not been made.

AND for the same consideration, said assignors hereby covenant and agree to and with said assignee its successors, legal representatives and assigns, that, at the time of execution and delivery of these presents, said assignors are the sole and lawful owners of the entire right, title and interest in and to said inventions and the application for Letters Patent above-mentioned, and that the same are unencumbered and that said assignors have good and full right and lawful authority to sell and convey the same in the manner herein set forth.

AND for the same consideration, said assignors hereby covenant and agree to and with said assignee, its successors, legal representatives and assigns, that said assignors will, whenever counsel of said assignee, or the counsel of its successors, legal representatives and assigns, shall advise that any proceeding in connection with said inventions, or said application for Letters Patent, or any proceeding in connection with Letters Patent for said inventions in any country, including interference proceedings, is lawful and desirable, or that any division, continuation or continuation-in-part of any application for Letters Patent or any reissue or extension of any Letters Patent, to be obtained thereon, is lawful and desirable, sign all papers and documents, take all lawful oaths, and do all acts necessary or required to be done for the procurement, maintenance, enforcement and defense of Letters Patent for said inventions, without charge to said assignee, its successors, legal representatives and assigns, but at the cost and expense of said assignee, its successors, legal representatives and assigns.

AND said assignors hereby request the Commissioner of Patents to issue said Letters Patent of the United States to said assignee as the assignee of said inventions and the Letters Patent to be issued thereon for the sole use of said assignee, its successors, legal representatives and assigns.

1-22-01  
Date  
Gregory R. Mundy  
Gregory R. Mundy

1-22-01  
Date  
Ross I. Garrett  
Ross I. Garrett

1-22-01  
Date  
G. Rossini  
G. Rossini

STATE OF TEXAS  
COUNTY OF BEXAR

Subscribed to before me on this 22nd day of January 2001.

Christine A. Soto  
Christine A. Soto  
Notary Public

